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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,633	11/14/2006	Shite Sebastian	101713-01-5093-US	4672
28977 7590 01/11/2012 MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921				
EXAMINER				
OGUNBIYI, OLUWATOSIN A				
ART UNIT		PAPER NUMBER		
1645				
MAIL DATE		DELIVERY MODE		
01/11/2012		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/576,633

**Applicant(s)**

SEBASTIAN ET AL.

**Examiner**

OLUWATOSIN OGUNBIYI

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5) ☒ Claim(s) 1,2 and 4-12 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1,2 and 4-12 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-853)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/11 has been entered.

Claim 1 has been amended. Claims 3 and 13-22 are cancelled. Claims 1-2 and 4-12 are pending and are under examination.

***Claim Rejections Withdrawn***

The rejection of claims 1-2 and 4-12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment to the claims.

The rejection of claims 1-2 and 4-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment to the claims.

The rejection of claims 1-2, 4-6 and 8-12 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment to the claim.

***New Claim Rejections***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, it is not clear whether the substrate is labeled with the fluorescent probe and quencher dye in addition to the at least one detectable moiety in claim 1 or whether the fluorescent probe and quencher dye are the at least one detectable moiety.

In claim 5, it is not clear whether the substrate is labeled with the labels listed in addition to the at least one detectable moiety in claim 1 or whether the labels of claim 5 are the at least one detectable moiety.

Claim 7 recites the limitation "wherein the sample is selected from the group consisting of a wound surface on a subject and a fluid from a wound on a subject". There is insufficient antecedent basis for this limitation in claim 1 from which the claim depends. In claim 1 the samples are already listed to be selected from a wound, a body fluid or fluid from a wound. There is no mention of fluid from a wound on a subject or wound surface on a subject.

Claim 8 recites "the surface to which said substrate is attached..." The amendment to claim 1 removes the reference to "a surface attached". Thus, "the surface to which said substrate is attached..." lacks antecedent basis.

Claim 11, it is not clear whether the substrate is further attached to the listed solid supports or claim 11 further describes the support coupled to the substrate in claim 1. If the claim interpretation is the latter, then claim 11 line 2 should be "...and the support is a solid support surface selected from..." instead of "... and the substrate is attached to a solid support surface selected from..."

In claim 11, it is not clear whether the at least two dissimilar colorimetric components are the at least one detectable moiety of claim 1 or the at least two dissimilar colorimetric components are separate from the detectable moiety of claim 1.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1, 2 and 5-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 7,8,10, 11, 12 and 15 of copending Application No. 10/576, 634 ('634). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '634 claims disclose a method of detecting the presence or absence of a pathogenic microorganism in a sample selected from a wound surface, body fluid comprising contact the sample with detectably labeled (colorimetric) substrate i.e. is SEQ ID NO: 21 or 22 or 23 identical to SEQ ID NO: 1,2 and 5 respectively under conditions that result in cleavage of said substrate by a protein produced by said pathogenic microorganism wherein said substrate is couple to both the colorimetric detectable moiety and a support (see claim 1-3 and 8, for example) and detecting a cleavage or an absence of the cleavage of the substrate, the cleavage of the substrate indicating the presence of the pathogen of interest in the wound surface or body fluid. The '634 application discloses

that SEQ ID NO: 21 or 22 or 23 and the instant specification (see examples) disclose that SEQ ID NO: 1, 2 and 5 are cleaved by the presence of bacterium i.e. proteases produced by bacteria. The declaration under 37 CFR 1.132 by the inventor filed 9/8/09 states in the manuscript discussion section p. 24 of 26 that the CPI2 peptide was shown to be clipped by secreted proteases from bacterial species such as *S. aureus* prevalent in wound and is a broad spectrum substrate for bacterial proteases. Therefore, the use of SEQ ID NO: 21 or 22 or 23 in the '634 claims for detection of bacteria is prima facie obvious as these peptides are inherently substrates for bacterial proteases.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### *Status of Claims*

Claims 1, 2, and 4-12 are rejected. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is (571)272-9939. The examiner can normally be reached on M-F 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Oluwatosin Ogunbiyi/

Primary Examiner, Art Unit 1645